EXHIBIT A
(Swartz CV)

Michael Swartz, PhD

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CONSULTING ANALYTICAL CHEMIST

Analytical Chemist with significant experience in drug development and discovery, business development, marketing, and chromatographic and spectroscopic method development and validation. Globally recognized leader in analytical chemistry, analytical method development and validation, chromatography, pharmaceutical chemistry, and regulatory compliance. History of consulting for private industry and trade organizations, along with lecturing worldwide. Known for excellent multi-tasking, supervisory, organizational, and hands-on problem-solving skills.

CORE COMPETENCIES

Chromatography | Method Development | Drug Development | Mass Spectrometry | Validation | Technical Writing
Biotechnology | Formulation Development | Research & Development (R&D) | Good Manufacturing Practice (GMP)

PROFESSIONAL EXPERIENCE

VALIDATION SCIENCE, Cotuit, MA (https://validationscience.com) **2024-Present**
Innovative consulting services for Pharmaceutical, Biotech, and Legal clients.
CEO, Head Consultant

- Providing analytical development and validation support from discovery to commercialization.
- Oversee management of outsourcing vendors.
- Expert witness for pharmaceutical and environmental litigation.

KARUNA THERAPEUTICS (BRISTOL MYERS SQUIBB), Boston, MA **2020 - 2024**
First-in-class therapies for serious neuropsychiatric disorders.
Executive Director, Analytical Development, 2022 - Present
Authored Module Three of the FDA-approved drug COBENFY™ (xanomeline and trospium chloride), a first-in-class muscarinic agonist for the Treatment of Schizophrenia in Adults.

- Oversaw the Contract Research Organizations (CROs), vendors, and other suppliers to ensure work quality, timeliness, and budget adherence.
- Managed the selection and performance of CROs, Contract Laboratories, and other vendors for assigned programs in collaboration with internal cross-functional disciplines.
- Represented the company at external project meetings, as required.
- Directed and managed financial planning/forecasting and budget management and monitored the budget against actuals.
- Functioned as chromatography (and other chemical and physical testing) subject matter expert (SME) to troubleshoot challenges encountered during method implementation or transfer to contractors.
- Authored and edited analytical CMC sections of NDA/IND/IMPD applications and amendments in collaboration with Regulatory Compliance and Quality Assurance Departments.
- Managed reference standard and stability programs and chaired specifications committee.
- Recruited, staffed, and mentored the Analytical Development and Bioanalytical Science group of 12 people.

Senior Director, Analytical Development, 2020 - 2022

- Directed method development, validation, and transfer activities at multiple CDMOs/CROs supporting drug substance (DS) and drug product (DP) manufacturing, release, stability testing, process chemistry support, and bioanalytical method development, validation, and testing.
- Functioned as chromatography (and other chemical and physical testing) SME to troubleshoot challenges encountered during method implementation or transfer to contractors.
- Authored and edited analytical CMC sections of IND/IMPD applications and amendments in collaboration with Regulatory Compliance and Quality Assurance Departments.
- Managed reference standard and stability programs and chaired specifications committee.
- Recruited and staffed the Analytical Development group with four direct reports.

STEALTH BIOTHERAPEUTICS, Newton, MA **2015 - 2020**
Innovation in mitochondrial therapies.
Director, Analytical Development

- Directed the method development, validation, and transfer activities at multiple CDMOs/CROs supporting drug substance (DS) and drug product (DP) manufacturing, release, stability testing, and process chemistry support.
- Functioned as chromatography (and other chemical and physical testing) SME to troubleshoot challenges encountered during method implementation or transfer to contractors.
- Provided leadership by chairing the Specification Committee to draft new and revise existing DS and DP specifications.
- Authored and edited analytical CMC sections of IND/IMPD/NDA applications and amendments in collaboration with Regulatory Compliance and Quality Assurance Departments.
- Managed the reference standard program.

BOSTON ANALYTICAL, Salem, NH **2014 - 2015**
Premier analytical testing services.
Director, Analytical Development and Validation

- Built a department of 5 chemists to provide analytical support to various pharmaceutical, biopharmaceutical, medical device, and healthcare companies worldwide.
- Served as SME for troubleshooting and development activities.
- Identified new business opportunities and evaluated and implemented new technologies supporting new business initiatives.
- Served as a member of the senior leadership staff and trained and mentored personnel while implementing new instruments and software technology.
- Acted as internal and external consultant, coordinating client services and project management.

ARIAD PHARMACEUTICALS INC., Cambridge, MA **2011 - 2013**
Global biotechnology company.
Principal Scientist, Analytical Development

- Performed method development using various analytical techniques in support of drug substance (DS) and drug product (DP) manufacturing, release, stability testing, and process chemistry support.
- Simultaneously directed phase-appropriate validation, transfer, and implementation of analytical methods at 6+ contract manufacturing organizations (CMO) to support GMP DS and DP manufacture, release, and stability testing.
- Wrote, edited, and approved the validation, transfer, and development protocols and reports.
- Set specifications for all DP and DS manufacturing processes in collaboration with the QC department.
- Authored and edited appropriate analytical sections of IND applications and amendments in collaboration with the Regulatory Compliance Department.
- Provided technical leadership, training, and mentoring to junior staff to optimize scientific contributions to the analytical development team.
- Contributed technical and regulatory expertise to CMC development project teams, specification review, and stability committees.

SYNOMICS PHARMA SERVICES. LLC., Wareham, MA **2007 - 2011**
Pharmaceutical contract research organization.
Research Director

- Supervised a staff of chemists to deliver GMP contract research method development and validation services to multiple pharmaceutical clients.
- Authored supporting documentation, including proposals, protocols, and reports.
- Evaluated and implemented new technology, resulting in several new service offerings, including dissolution testing, charged aerosol detection (CAD) technology for HPLC, Ultra Performance liquid chromatography (UPLC), and headspace-gas Chromatography (HS-GC).

WATERS CORPORATION, Milford, MA **2000 - 2007**
Separation science instrumentation.
Principal Consulting Scientist, Pharmaceutical Market Development

- Coordinated worldwide business development and marketing support for instrumentation sales to the pharmaceutical industry, providing pre- and post-sales support.
- Organized and presented on-site and webcast customer technology seminars worldwide that demonstrated diagnostic problem-solving approaches to challenges in the pharmaceutical laboratory.

- Developed HPLC, UPLC, and LC-MS applications for publication and presentation at international trade shows and technical conferences.
- Participated in several project teams responsible for bringing new technologies to the market, including UPLC, implemented marketing plans, managed budgets, and forecasted and tracked business.

ADDITIONAL RELEVANT EXPERIENCE

Applied research and development roles in chiral analyses, dissolution testing, impurity, content, and stability assays. Leadership role to patent and bring to market chiral reagents for the study of enantiomeric drugs.

EDUCATION

Doctor of Philosophy (PhD) in Analytical Chemistry
UNIVERSITY OF RHODE ISLAND, Kingston, RI
Thesis: “Separation and Identification of Enantiomeric Compounds by Liquid Chromatography and Micellar Electrokinetic Capillary Chromatography”

Master of Science (MS) in Analytical Chemistry
NORTHEASTERN UNIVERSITY, Boston, MA
Thesis Research Option.

Master of Science (MS) in Forensic Chemistry
NORTHEASTERN UNIVERSITY, Boston, MA
Thesis Research Option.

Bachelor of Science (BS) in Chemistry; Minor in Sociology/Criminology
SUNY COLLEGE AT CORTLAND, Cortland, NY

PATENTS

* Awards and Distinctions and a complete list of over 90 Publications, 225 Presentations, and 5 US Patents are available upon request.

TECHNICAL SKILLS

- GMP, CRO/CMO facilitation and management.
- Separation and identification of both small molecule synthetic and biologic pharmaceutical compounds using technology including High-Performance Liquid Chromatography (HPLC) Capillary to Preparative Scale, Ultra Performance Liquid Chromatography (UPLC), Capillary Electrophoresis (CE), and Gas Chromatography (GC)
- Mass Spectroscopy (MS and MS/MS), Ultraviolet (UV), and Infrared (IR) spectroscopy.
- Dissolution, Karl Fischer (KF), Chiral (enantiomer) Assays.
- Waters Empower, Millennium, MassLynx, Agilent Chemstation CDS software, Microsoft Excel, PowerPoint, and many additional software packages and client/server networks.